

FILING BY "EXPRESS MAIL" UNDER 37 CFR 1.10

EL 913014042 US  
Express Mail Label Number

February 13, 2002  
Date of Deposit

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF

ROSA MARTANI

APPLICATION NO: Not Yet Assigned

FILED: Herewith

FOR: RAPIDLY DISSOLVING DOSAGE FORM AND PROCESS FOR  
MAKING SAME

Assistant Commissioner for Patents  
Washington, D.C. 20231

PRELIMINARY AMENDMENT

Sir:

Prior to the examination of the above-referenced patent application, please amend the application as follows:

**In the Specification:**

Please insert the following after the title, page1,

-- This application is a continuation of International PCT Patent Application No. PCT/EP00/07934, filed August 14, 2000, which in its entirety is herein incorporated by reference. --.

**In the Claims:**

Please amend claims 4-10, 18-19 and 21-26 as follows:

4. (Amended) A process according to claim 1, where in step (b) the auxiliary solvent is selected from water, ethanol, acetone, isopropanol and any mixtures thereof.

5. (Amended) A process according to claim 1, where in step (c) the density of the compacted powder or granulate prepared is between 300 and 1000 mg/ml.

6. (Amended) A process according to claim 1, where in step (c) the density of the compacted powder or granulate is between 400 and 900 mg/ml.

7. (Amended) A process according to claim 1, where in step (c) the amount of powder or granulate which is subjected to compaction contains the intended dose of the active substance.

8. (Amended) A process according to claim 1, where in step (e) the auxiliary solvent is removed by applying simultaneously or interchangeably at least two different techniques selected from forced warm gas, microwave radiation and reduced pressure.

9. (Amended) A process according to claim 1, where in step (e) the auxiliary solvent is removed by applying simultaneously a combination of forced warm gas and microwave radiation.

10. (Amended) A process according to claim 1, wherein a solid pharmaceutical or veterinary dosage form for oral administration is manufactured.

18. (Amended) A solid pharmaceutical dosage form for oral administration according to claim 12, wherein the active substance is selected from the group consisting of (a) diclofenac, ketoprofen, ibuprofen, aspirin, paracetamol, melatonin and pharmaceutically acceptable salts thereof, and (b) pharmaceutically acceptable salts of calcium, magnesium and zinc.

19. (Amended) A solid pharmaceutical or veterinary dosage form for oral administration according to claim 15, wherein the composition contains as other usual excipients (4) a lubricant and optionally other usual excipients.

21. (Amended) A solid pharmaceutical or veterinary dosage form for oral administration according to claim 15, wherein the composition contains as other usual excipients (4) a lubricant, one or more sweeteners and optionally other usual excipients.

22. (Amended) A solid pharmaceutical or veterinary dosage form for oral administration according to claim 12, wherein the filler (2) is present in an amount of at least 30 weight-%, and the disintegrating agent (3) is present in an amount of from 0.5 up to 15 weight-% of the total dosage form.

23. (Amended) A solid pharmaceutical or veterinary dosage form for oral administration according to claim 15, which dosage form is manufactured without applying any compression force to the mixture of the components (1), (2), (3) and optionally (4) during the last step of manufacture concerning the solid dosage form.

24. (Amended) A solid pharmaceutical or veterinary dosage form for oral administration according to claim 12, which dosage form is manufactured without applying any freeze-drying process.

25. (Amended) A solid pharmaceutical or veterinary dosage form for oral administration according to claim 15, which dosage form is manufactured by starting with the preparation of a homogeneous mixture of all the components (1), (2), (3) and optionally (4) of the dosage form.

26. (Amended) A solid dosage form according to claim 12, which is intended for the pharmaceutical field.

#### **Remarks**

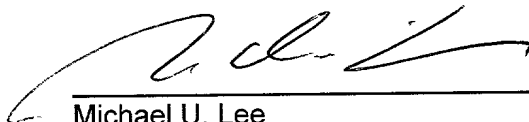
Applicant submits that claims 4-10, 18-19 and 21-26 have been amended to remove multidependence of the claims.

Attached hereto is a marked-up version of the changes made to the claims by the

current amendment. The attached pages are captioned "VERSION WITH MARKINGS TO  
SHOW CHANGES MADE."

Respectfully submitted,

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Date: 2/13/02

**VERSION WITH MARKINGS TO SHOW CHANGES MADE**

**In the Claims:**

Claims 4-10, 18-19 and 21-26 have been amended as follows:

4. (Amended) A process according to claim 1 ~~any one of claims 1-3~~, where in step (b) the auxiliary solvent is selected from water, ethanol, acetone, isopropanol and any mixtures thereof.

5. (Amended) A process according to claim 1 ~~any one of claims 1-4~~, where in step (c) the density of the compacted powder or granulate prepared is between 300 and 1000 mg/ml.

6. (Amended) A process according to claim 1 ~~any one of claims 1-4~~, where in step (c) the density of the compacted powder or granulate is between 400 and 900 mg/ml.

7. (Amended) A process according to claim 1 ~~any one of claims 1-6~~, where in step (c) the amount of powder or granulate which is subjected to compaction contains the intended dose of the active substance.

8. (Amended) A process according to claim 1 ~~any one of claims 1-7~~, where in step (e) the auxiliary solvent is removed by applying simultaneously or interchangeably at least two different techniques selected from forced warm gas, microwave radiation and reduced pressure.

9. (Amended) A process according to claim 1 ~~any one of claims 1-7~~, where in step (e) the auxiliary solvent is removed by applying simultaneously a combination of forced warm gas and microwave radiation.

10. (Amended) A process according to claim 1 ~~any one of claims 1-9~~, wherein a solid pharmaceutical or veterinary dosage form for oral administration is manufactured.

18. (Amended) A solid pharmaceutical dosage form for oral administration according to claim 12 ~~any one of claims 12-17~~, wherein the active substance is selected from the group consisting of (a) diclofenac, ketoprofen, ibuprofen, aspirin, paracetamol, melatonin and pharmaceutically

acceptable salts thereof, and (b) pharmaceutically acceptable salts of calcium, magnesium and zinc.

19. (Amended) A solid pharmaceutical or veterinary dosage form for oral administration according to claim 15 ~~any one of claims 12-18~~, wherein the composition contains as other usual excipients (4) a lubricant and optionally other usual excipients.

21. (Amended) A solid pharmaceutical or veterinary dosage form for oral administration according to claim 15 ~~any one of claims 12-20~~, wherein the composition contains as other usual excipients (4) a lubricant, one or more sweeteners and optionally other usual excipients.

22. (Amended) A solid pharmaceutical or veterinary dosage form for oral administration according to claim 12 ~~any one of claims 12-21~~, wherein the filler (2) is present in an amount of at least 30 weight-%, and the disintegrating agent (3) is present in an amount of from 0.5 up to 15 weight-% of the total dosage form.

23. (Amended) A solid pharmaceutical or veterinary dosage form for oral administration according to claim 15 ~~any one of claims 12-22~~, which dosage form is manufactured without applying any compression force to the mixture of the components (1), (2), (3) and optionally (4) during the last step of manufacture concerning the solid dosage form, ~~i.e. process step (e)~~.

24. (Amended) A solid pharmaceutical or veterinary dosage form for oral administration according to claim 12 ~~any one of claims 12-23~~, which dosage form is manufactured without applying any freeze-drying process.

25. (Amended) A solid pharmaceutical or veterinary dosage form for oral administration according to claim 15 ~~any one of claims 12-24~~, which dosage form is manufactured by starting with the preparation of a homogeneous mixture of all the components (1), (2), (3) and optionally (4) of the dosage form.

26. (Amended) A solid dosage form according to claim 12 ~~any one of claims 12-25~~, which is intended for the pharmaceutical field.